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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,838	10/16/2006	Claudine Elvire Marie Bruck	VB60528	2078

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
07/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,838	BRUCK ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26, 33-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. This application is a 371 of PCT/EP04/11620. For applications filed under 371, PCT rules for lack of unity apply.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-2, are drawn to a method of enhancing an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant.

Group 2. Claims 3-9, 26, 27-32, are drawn to a method of reducing the severity of a cancer in a patient, comprising administering to a patient in need thereof a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof and 2) an immunogenic composition comprising a tumour-associated antigen or immunogenic derivative thereof and a saponin adjuvant.

Group 3. Claims 10-21, 25, are drawn to a composition comprising as active ingredients the following individual components: (1) IL-18 polypeptide or bioactive fragment or variant thereof and (2) immunogenic composition comprising an antigen and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

Group 4. Claims 22-24, drawn to a kit comprising as active ingredients (1) an IL-18 polypeptide or bioactive fragment thereof and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant.

Group 5. Claims 33-38, drawn to a method for prophylaxis of infectious disease in a patient already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

Group 6. Claims 33-38, drawn to a method for prophylaxis of cancer in a patient already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

Group 7. Claims 33-38, drawn to a method for prophylaxis of autoimmune disease in a patient already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

Group 8. Claims 33-38, drawn to a method for treatment of infectious disease in a patient already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

Group 9. Claims 33-38, drawn to a method for treatment of cancer in a patient already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

Group 10. Claims 33-38, drawn to a method for treatment of autoimmune disease in a patient already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

NOTE: Claims 33 and 34 are duplicate. Appropriate correction is required in response to this action.

The inventions listed as Groups I-10 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since US Patent No. 6,375,945 teaches a method of enhancing an immune an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof (which encompasses the cytokine IL-12), and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant (see column 1, lines 14-24; column 3, lines 31-column 4, line 33, and claims). Therefore the reference teaches a method meeting the limitations of the claims of Group I.

Since the first claimed invention lacks a special technical feature, the other claimed invention cannot share a special technical feature with the first claimed invention. The invention of Groups 2, 4-10 are patentably distinct from the method of Group I because each method uses method steps, results steps, and patient populations not required by the other and the search of all methods in one application would result in an undue search burden. The invention of Group 3 is

patentably distinct from the inventions of Groups 1-2, 4-10, because the composition of Group 3 can be used in the production of specific antigens.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Election of Species

4a. This application contains claims directed to the following patentably distinct species of antigen of the claimed invention:

If Group I is elected, Applicants are required to elect one of the following species of antigen selected from:

an organism selected from the group consisting of :Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus, Varicella Zoster Virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from Neisseria spp, Moraxella

spp, Bordetella spp; Mycobacterium spp., including M. tuberculosis; Escherichia spp, including enterotoxic E. coli; Salmonella spp.,; Listeria spp; Helicobacter spp; Staphylococcus spp., including S. aureus, S. epidermidis; Borrelia spp; Chlamydia spp., including C. trachomatis, C. pneumoniae; Plasmodium spp., including P. falciparum; Toxoplasma spp., and Candida spp.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of TSLP activity for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4b. This application contains claims directed to the following patentably distinct species of tumor associated antigen of the claimed invention:

If any one of Group 2 or Group 3 or Group 4 is elected, Applicants are required to elect one of the following species of antigen selected from:

an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of TSLP activity for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3-9, 10-12, 14-21, 25, 22-23, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4c. This application contains claims directed to the following patentably distinct species of immunochemical stimulant of the claimed invention:

If Group 3 is elected, Applicants are required to elect one of the following species of immunochemical stimulant selected from:

3D-MPL, cholesterol, CpG oligonucleotide containing at least one immunostimulatory CG dinucleotide, aluminium hydroxide, aluminium phosphate, and tocopherol, and an oil in water emulsion.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of TSLP activity for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10-16, 18-21, 25, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646